NOV 18 2011

5 510(k) Summary

Date Prepared:	May 23, 2011
Submitter/Importer/Distributer Name:	Translational Sciences Corporation
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Submitter's Phone:	617.297.2577
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Contact:	Howard Pinsky, Chief Executive Officer
Manufacturer:	Mint Medical Systems, GmbH Im Neuenheimer Feld 582 D-69120 Heidelberg Germany
Proprietary Name:	OncoTrac™
Common Name:	Software PACS
Classification:	892.2050 Picture archiving and communications system, Product Code LLZ, (Class II)
Substantially Equivalent to:	Tradename: AW Server Manufacturer: General Electric Medical Systems 510(k) Number: K081985

Device Description:

OncoTrac™ is a software based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and visualization of medical image data. It provides for communication, storage, processing, rendering, and display of DICOM compliant image data derived from various sources including CT and MRI.

OncoTrac™ runs on either a native or virtualized Microsoft Windows platform. Available functions include communication, storage, processing, rendering, and display of DICOM compliant image data derived from various sources including CT and MRI, measurement of lesions identified by trained users, tabulation of measurements, categorization of tumor response in accordance with user selected standards, and generation of a structured imaging report. The user controls these functions with a system of interactive menus and tools.

The OncoTrac™ software has been extensively tested on Windows 64 bit systems by members of the development and quality control teams. A hazard analysis has been conducted and the level of concern has been classified as moderate. The release version of the software passed all tests considered critical in terms of patient safety and demonstrated an overall acceptable performance.

Substantial Equivalence Comparisons to Predicate Devices:

Feature	OncoTrac™	GE AW Server (primary predicate)
510k number		K081985
DICOM compliance	yes	yes
2D Imaging	2D image viewer	Same plus 3D viewer
Interactive user controls	yes	yes
lesion measurement	yes	yes
body region(s)	multiple	multiple
modalities	CT, MRI	CT, MRI
Quantitative oncology response assessment	RECIST WHO	RECIST WHO
Generation of structured report	pdf	same
Prescription Use	Yes	same
Intended Users	Trained Professionals	same

Intended Use:

OncoTrac™ is a software based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and visualization of medical image data. It provides for communication, storage, processing, rendering, and display of DICOM compliant image data derived from various sources including CT and MRI, measurement of lesions identified by trained users, tabulation of measurements, categorization of tumor response in accordance with user selected standards, and generation of a structured imaging report.

OncoTrac™ is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists, and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. OncoTrac™ does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure, or function.

OncoTrac™ is not intended for use for mammography.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Allen Green, MD, PHD, NJ, LLC
Counsel
Translational Sciences Corporation
One Mifflin Place, Suite 400
CAMBRIDGE MA 02138

NOV 18 2011

Re: K111642
Trade/Device Name: OncoTrac
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 2, 2011
Received: November 4, 2011

Dear Mr. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Applicant: Translational Sciences Corporation.
One Mifflin Place, Suite 400
Cambridge, MA 02138

510(k) Number (if known): K111642

Device Name: OncoTrac™

Indications for Use:

OncoTrac™ is a software based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and visualization of medical image data. It provides for communication, storage, processing, rendering, and display of DICOM compliant image data derived from various sources including CT and MRI, measurement of lesions identified by trained users, tabulation of measurements, categorization of tumor response in accordance with user selected standards, and generation of a structured imaging report.

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OncoTrac™ is not intended for use for mammography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111642